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APPLICATION NO.	FILING DATE	FIRST-NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,932	01/16/2002	Peter Hagerlid	14256	2854
7590	03/22/2005		EXAMINER	
Dorsey & Whitney 250 Park Avenue New York, NY 10177			GORDON, BRIAN R	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,932

Applicant(s)

HAGERLID ET AL.

Examiner

Brian R. Gordon

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1-6-05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 16-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 16, 17 and 19 is/are rejected.
- 7) ☒ Claim(s) 18 and 20-23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 19 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1-28-025; 1-22, 02.</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 18 and 20-23 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 18 and 20-23 have not been further treated on the merits.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The section headings are missing from the specification.

2. The disclosure is objected to because of the following informalities: reference numeral 28 is directed to both the cannula and foil seal (page 11).

Appropriate correction is required.

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not support the reservoir being closed at indicated by claim 1. The nozzle when mounted does not completely close the end of the reservoir as claimed, for the nozzle has an opening which is not closed as such the reservoir is not closed.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "an outlet member mounted so as to close an opening in the liquid reservoir." The examiner assumes applicant is referring to the nozzle element of

Art Unit: 1743

the invention. The nozzle has an opening that remains open therefore the nozzle is not mounted to close an end of the reservoir. It is unclear how the nozzle can close and end of the reservoir when the nozzle itself is open; therefore reservoir is not closed as claimed.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-4, 17, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Madden et al. US 6,783,732.

Madden et al. discloses a device comprises a plurality of reservoirs with outlets as claimed by applicant. Specifically provides multi-well plates and column arrays in which samples (e.g., cell lysates containing nucleic acids of interest, such as RNA) can be analyzed and/or processed. In one embodiment, the microfiltration arrangement is a multilayer structure, including (i) a column plate having an array of minicolumns into which samples can be placed, (ii) a discrete filter element disposed in each minicolumn, (iii) a drip-director plate having a corresponding array of drip directors through which filtrate may egress, and (iv) a receiving-well plate having a corresponding array of

Art Unit: 1743

receiving wells into which filtrate can flow. The invention provides multi-well microfiltration arrangements that are relatively simple to manufacture and that overcome many of the problems associated with the prior arrangements relating to (i) cross-contamination due to wicking across a common filter sheet or (ii) individual filter elements entrapping sample constituents within substantial dead volumes. Further, the invention provides multi-well microfiltration arrangements that adequately support discrete filter elements disposed in the wells without creating substantial preferential flow. Additionally, the invention provides multi-well microfiltration arrangements that avoid cross-contamination due to aerosol formation, pendent drops and/or splattering (abstract).

As seen in Figure 3, the device comprises a plurality of wells 18 (cartridges) including a minicolumn 12 (reservoir) with a protruding nozzle or drip director 16 with an open aperture mounted to the end of the minicolumn (column 11, lines 37-54).

The device is further sealed by the wall 20a at the end opposite the nozzle (column 12 lines 48-55).

Liquid may be forced out of the columns using high pressure of a vacuum source.

8. Claims 1-4, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Bankier et al. US 5,846,493.

Bankier et al. discloses a system is provided for filtering a substance from a solution for subsequent analysis of the substance. The system has a manifold and a removable cover capable of latching onto a base defining an interior of the manifold.

Art Unit: 1743

Apertures are formed in the cover capable of receiving columns having a filter for filtering the substance from the solution as solution is drawn through the columns into the manifold. The columns may be integrally formed to provide a set of columns. As a result, an array of apertures can receive a number of sets of columns to conduct the filtering process (abstract).

As seen in Figure 5, each column (cartridge) has a reservoir and a tapered nozzle with an opening protruding from one end.

9. Claims 1-4, 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Wannlund US 5,0355,866.

Wannlund discloses an apparatus for performing and measuring chemical reactions includes a reaction test apparatus having reaction wells wherein reactants are controllably mixed, and exposure apparatus which receives and positions the reaction test apparatus adjacent a photographic film. Each of the reaction wells includes at least two reaction cups, arranged one above the other. The uppermost reaction cups have orifices in the bottoms, so that liquid can be mixed and reacted in the uppermost cup, and then controllably transferred to the lower cup to be mixed with additional reactants. In a preferred embodiment, the reaction cups are supported in plates that are structurally integral with the cups, and are superimposed to make a test block. The test block is retained in the exposure apparatus, and liquid is forced from the upper cup to the lower cup by application of pressure to the top of the upper cup. The apparatus of the invention is particularly suited for measuring reactions that produce luminescence of

Art Unit: 1743

short duration, as the reactants can be conveniently mixed in darkness, while the film is being exposed (abstract).

As seen in FIGS. 2 and 3, each test well 28 includes an upper reaction cup 30 (cartridge) and a lower reaction cup 32. One upper reaction cup 30 for each test well 28 is molded into the upper plate 24 (cassette). Each cup 30 and 32 has an open top and sides that taper inwardly from the top to the bottom (nozzle) of the cup. The upper reaction cup 30 has an orifice 40 in the bottom thereof. The orifice 40 is closed by a removable plug 42, preferably a small amount of chemically inert silicone laboratory grease. An increased internal pressure within the upper reaction cup 30, as controllably applied by the exposure apparatus 22, causes the plug 42 to be ejected. Ejection of the plug 42 opens the orifice 40 (nozzle aperture), so that any liquid therein falls downwardly into the lower reaction cup 32, which is positioned directly below the upper reaction cup 30 in their nesting relationship.

To retain the chemical reactants in the cups 30 and 32, and to prevent their contamination, a foil cover 48 is preferably sealed over the top of the upper plate 24. In use, the foil cover 48 is removed or punctured when a particular test well 28 is used, and this physical disruption of the foil cover 48 serves as an indicator of which test wells 28 have been used (column 8, line 4 – column 9 line 15).

The invention is used for analysis of the bacteriuria content of urine samples. This test depends upon the reaction of bacterial ATP with luminescent reagents, to produce light that is measured on the film 80 (column 13, lines 3-14).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Madden et al., Wannlund, or Bankier et al.

Art Unit: 1743

14. Madden et al., Wannlund, nor Bankier et al. recite the specific dimensions of the outlet port of the respective nozzles as having a diameter between 2 and 300 micrometers.

It would have been obvious to one of ordinary skill in the art at the time of the invention to recognize the respective devices may have been modified during the molding process of devices to incorporate a nozzle with an opening in the said range in order to precisely control the amount of test fluid exiting each reservoir.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hager; David C. et al.; Lehtinen; Kauko et al.; Ingenhoven; Nikolaus et al.; Brewer; William E; Inoue; Takaaki; Berndt, Manfred; Boulton; David A. et al.; Roberts; Roger Q. et al.; Elkins; Carlos D.; Franciskovich; Phillip P. et al.; Tremmel; Ewald et al.; Carrico, Jr.; Charles L. et al.; Kearney, Patrick et al.; Gordon; Virginia C. et al.; Zermani; Thomas G.; Blevins; Dennis D. et al.; Mack; Michael et al.; Boulton; David A. et al.; Gautsch; James W.; Astle; Thomas W.; Chateau; Sophie; Matkovich; Vlado I.; Clark; Phillip et al.; Root; David et al.; Bagshawe; Kenneth D.; and Fujii; Hideyo disclose fluid transfer devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

Art Unit: 1743

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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